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REMARKS**DISCUSSION OF SPECIFICATION**

The specification has been amended to correct typographical informalities. Applicant respectfully requests acceptance of the amended specification because no substantive new matter has been added.

DISCUSSION OF CLAIMS

In the Office Action, claims 6 and 11-20 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

In the Office Action, claims 1-3, 5-9, 11-13 and 21 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent Number 4,969,460 to Callaghan et al.

In the Office Action, claims 4 and 14-15 are rejected under 35 U.S.C. §103(a) as being unpatentable over Callaghan et al. in view of U.S. Patent Number 5,554,174 to Causey, III.

In the Office Action, claims 10 and 16-20 are rejected under 35 U.S.C. §103(a) as being unpatentable over Callaghan et al. in view of U.S. Patent Number 5,127,402 to Mann et al.

In response thereto, claims 6, 11, 13, 15, and 17 have been amended. Accordingly, claims 1-21 are now pending. Following is a discussion of the patentability of each of the pending claims.

Preliminary Matter

In response to the rejections under 35 U.S.C. §112, second paragraph, the following amendments have been made:

claim 6, lines 1-2, "determining a characteristic comprises determining whether" has been replaced with --change in the--;

claim 6, lines 2-3, "being changed is the" has been replaced with --comprises an--;

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claim 6, line 3, --a-- has been inserted between "or" and "ventricular";

claim 11, line 13, the first occurrence of "the" has been replaced with --a-- and the second occurrence of "the" has been replaced with --a--;

claim 13, line 1, "11" has been replaced with --12--;

claim 15, line 1, "13" has been replaced with --14--; and

claim 17, line 1, "15" has been replaced with --16--.

Independent Claim 1

Claim 1 recites a method for operating an implantable cardiac stimulation device that dynamically modifies a pacing pulse energy. The method comprises determining whether one or more operating parameters require adjustment in response to a change in the pacing pulse energy and adjusting a value for an operating parameter to a new value if the operating parameter requires adjustment. The new value is based upon the pacing pulse energy.

The *Callaghan et al.* reference discloses automatic output regulation (control of output energy) in a pacemaker to determine the lowest possible pulse output energy which results in heart capture. One of the problems encountered during automatic output regulation is a fusion beat, which is a combined intrinsic and paced event. A fusion beat is difficult to sense and can lead to an erroneous determination that there has been a loss of capture and, thus, there is a need to increase output energy. In order to distinguish between a fusion beat and a loss of capture, in the event of an apparent loss of capture, pacing rate is increased slightly to avoid the possibility of fusion beats. Furthermore, a high energy back-up pulse is generated shortly after the failure to sense an evoked response from the preceding ordinary stimulus. If the back-up pulse fails to evoke a response, it is an indication that the preceding stimulus resulted in a fusion beat. If the back-up pulse gives rise to an evoked potential, the preceding stimulus resulted in heart capture failure.

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The *Callaghan et al.* reference does not disclose or suggest determining whether one or more operating parameters require adjustment in response to a change in the pacing pulse energy and adjusting a value for an operating parameter to a new value, wherein the new value is based upon the pacing pulse energy. In the *Callaghan et al.* reference, pacing rate is increased to avoid the possibility of fusion beats. As such, increasing the pacing rate is directed to resolving a "timing issue" whereas claim 1 of the present application is directed to adjusting operating parameters based upon a change in the pacing pulse energy. In other words, the pacing rate is increased to ensure that a pacing pulse precedes an intrinsic event. In the event of an apparent loss of capture during an automatic output regulation, the value of the pacing rate is not dependent upon a change in pacing pulse energy. The increase in pacing rate is based upon decreasing the escape interval sufficiently such that a pacing pulse precedes an intrinsic event to avoid fusion beats.

The *Causey, III* reference discloses an implantable cardiac device that provides cardioversion and defibrillation therapies. The device forecasts time-to-therapy based on battery voltage degradation and provides an enhanced energy shock in the event a predetermined threshold time is reached. The device further monitors elapsed time-to-therapy to determine whether the predetermined threshold time is exceeded and sets the energy content of the therapeutic shock accordingly.

Nowhere does the *Causey, III* reference disclose or suggest determining whether one or more operating parameters require adjustment in response to a change in the pacing pulse energy and adjusting a value for an operating parameter to a new value if the operating parameter requires adjustment, wherein the new value is based upon the pacing pulse energy. The *Causey, III* reference is directed to forecasting time-to-therapy based on battery performance.

The *Mann et al.* reference discloses an implantable stimulation device that limits the utilization of high power consumption modes during low battery periods. When the battery is below a predetermined threshold, the implantable stimulation device is switched from a high current drain mode of operation to progressively lower current drain modes of

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The *Callaghan et al.* reference does not disclose or suggest determining whether one or more operating parameters require adjustment in response to a change in the pacing pulse energy and adjusting a value for an operating parameter to a new value, wherein the new value is based upon the pacing pulse energy. In the *Callaghan et al.* reference, pacing rate is increased to avoid the possibility of fusion beats. As such, increasing the pacing rate is directed to resolving a "timing issue" whereas claim 1 of the present application is directed to adjusting operating parameters based upon a change in the pacing pulse energy. In other words, the pacing rate is increased to ensure that a pacing pulse precedes an intrinsic event. In the event of an apparent loss of capture during an automatic output regulation, the value of the pacing rate is not dependent upon a change in pacing pulse energy. The increase in pacing rate is based upon decreasing the escape interval sufficiently such that a pacing pulse precedes an intrinsic event to avoid fusion beats.

The *Causey, III* reference discloses an implantable cardiac device that provides cardioversion and defibrillation therapies. The device forecasts time-to-therapy based on battery voltage degradation and provides an enhanced energy shock in the event a predetermined threshold time is reached. The device further monitors elapsed time-to-therapy to determine whether the predetermined threshold time is exceeded and sets the energy content of the therapeutic shock accordingly.

Nowhere does the *Causey, III* reference disclose or suggest determining whether one or more operating parameters require adjustment in response to a change in the pacing pulse energy and adjusting a value for an operating parameter to a new value if the operating parameter requires adjustment, wherein the new value is based upon the pacing pulse energy. The *Causey, III* reference is directed to forecasting time-to-therapy based on battery performance.

The *Mann et al.* reference discloses an implantable stimulation device that limits the utilization of high power consumption modes during low battery periods. When the battery is below a predetermined threshold, the implantable stimulation device is switched from a high current drain mode of operation to progressively lower current drain modes of

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operation. The *Mann et al.* reference does not disclose or suggest determining whether one or more operating parameters require adjustment in response to a change in the pacing pulse energy and adjusting a value for an operating parameter to a new value if the operating parameter requires adjustment, wherein the new value is based upon the pacing pulse energy. The *Mann et al.* reference is directed to reducing drain current at recommended replace time.

Accordingly, it is respectfully submitted that claim 1 is in condition for allowance.

Dependent Claims 2-7

Claims 2-7 depend from claim 1 and are similarly patentable. Accordingly, it is respectfully submitted that these claims are in condition for allowance.

Independent Claim 8

For at least the same reasons discussed above with regards to claim 1, it is respectfully submitted that claim 8 is in condition for allowance.

Dependent Claims 9 and 10

Claims 9 and 10 depend from claim 8 and are similarly patentable. Accordingly, it is respectfully submitted that these claims are in condition for allowance.

Independent Claim 11

For at least the same reasons discussed above with regards to claim 1, it is respectfully submitted that claim 11 is in condition for allowance.

Dependent Claims 12-20

Claims 12-20 depend from claim 11 and are similarly patentable. Accordingly, it is respectfully submitted that these claims are in condition for allowance.

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Independent Claim 21

For at least the same reasons discussed above with regards to claim 1, it is respectfully submitted that claim 21 is in condition for allowance.

CONCLUSION

In light of the above claim amendments and remarks, it is respectfully submitted that the application is in condition for allowance, and an early notice of allowance is requested.

Respectfully submitted,

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Date

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